UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,423	12/31/2001	Janette Lazarovits	10793/45	8825

26646 7590 12/01/2006

KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,423	LAZAROVITS ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/06 4/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS 7/14/05*.

Continuation of Disposition of Claims: Claims pending in the application are 18-20,22-30,32,34-49,51,53,60,61,68-72,75-80,82-86,88,96,103-107,110-115,117,118 and 155.

Continuation of Disposition of Claims: Claims rejected are 18-20,22-30,32,34-49,51,53,60,61,68-72,75-80,82-86,88,96,103-107,110-115,117,118 and 155.

DETAILED ACTION

Claims 1-17, 21, 31, 33, 50, 52, 54-59, 62-67, 73, 74, 81, 87, 89-95, 97-102, 108, 109, 116, 119-154 and 156-163 have been canceled. Claims 18-20, 22-30, 32, 34-49, 51, , 53, 60, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110, 111, 117 and 155 have been amended. Claims 18-20, 22-30, 32, 34-49, 51, , 53, 60, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-23, 25-30, 34-49, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155 are given the effective priority date of the instant filing on December 31, 2001. Claim 24 will be given the effective priority date of the provisional application.

Claim 24 remains objected to for the typographical error including "or" before "SEQ ID NO:20".

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-20, 23-30, 32, 34-49, 51, , 53, 60, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. .

Without any further limitation, the claims include antibodies which are found in vivo Thus the instant human antibodies read on natural antibodies found within humans, and the claims are rejected under 101 as being a product of nature. Amendment of the claims to recite "isolated" antibodies would overcome this rejection.

Claims 18-20, 23-30, 32, 34-49, 51, , 53, 60, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) As drawn to new matter

The instant claims have been amended to require human antibodies. The specification discloses that the human scFv antibodies Y1 and Y17 were isolated from a human antibody phage display library (page 39, paragraph 176) and further states that "One example of an antibody of the present invention that binds to epitopes of formulae I-III" is the fully human antibody Y1 (page 46, paragraph 193). These statements do not provide support for the amendment of the instant claims to human antibodies because the description of two individual antibody clones, Y1 and Y14, which were derived from a phage display library of human antibody sequences, do not adequately describe the claimed genus of antibody multimers which include any antibody which binds to the described sequence motif. One of skill in the art upon reading of the instant specification which describes two antibody clones extracted from a phage display library of human sequences would not conclude that the entire invention was restricted to only human antibodies which bound to the described sequence motif. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus of human antibody multimers at the time of filing.

(B)As drawn to inadequate written description

Claims 26-29 encompass an antibody which binds to a polypeptide epitope ranging from 3 to 126 amino acids in length and comprising at least 2 acidic amino acids and at least one sulfated amino acids. the specification describes the epitope of claims 18-20 and the proteins of PSGL-1, fibrinogen gamma prime, GPIBalpha, heparin, lumican, CC4 interalpha inhibitor and prothrombin which are bound by said antibodies which exhibit cross reactivity. Claims 26-20 are not limited to antibodies which bind the epitope as described in claim 18, nor to antibodies which bind to or cross-react with PSGL-1, fibrinogen gamma prime, GPIBalpha, heparin,

lumican, CC4 interalpha inhibitor and prothrombin. Therefore the genus of antibodies encompassed by claims 26-29 is highly variant, encompassing antibodies which bind to epitopes which do not resemble that of the epitope in claim 18, or having the same binding affinity for PSGL-1, fibrinogen gamma prime, GPIBalpha, heparin, lumican, CC4 interalpha inhibitor and prothrombin. The description of antibodies which bind to the epitope as set forth in claim 18 fails to describe the antibodies which bind to the epitope as described in claims 26-29 because the genus of epitopes encompassed in claims 26-29 encompasses members which differ in primary structure from the genus of epitopes to which the antibodies of claim 18 bind, and the genus of antibodies reliant on the genus of epitopes of claims 26-29 are not limited to the binding specificities and cross reactivities of the genus of antibodies limited to those which bind the epitope of claim 18. One of skill in the art would reasonable conclude that applicant was not in possession of the broadly claimed antibodies of claims 26-29.

Claims 30, 32, 34-37, 39, 45, 47, 48 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Arvieux et al (Blood, 1999, Vol. 93, pp. 4248-4255).

Arvieux et al disclose anti-cardiolipin antibodies isolated from the serum of human patients which cross react with complement 4b-binding protein, in combination with phospholipids and GPI-B2 and cardiolipin page 248, second column, lines 7-28, page 4249, Table 1 and page 4245, line 2 to page 4246, first column line 2). Thus, it appears that said antibodies have the required cross-reactivity between GPIBalpha and CC4 which fulfill the limitations of claims 30, 34, and that said antibodies bind an epitope that is a lipo conjugate which meets the limitations of claims 34 and 35. The reference does not specifically teach that the antibodies bind a polypeptide epitope conforming to the limitations of claim 155 and binding to PSGL-1, fibrinogen gamma prime and heparin in addition to GPIBalpha However, the claimed antibodies appears to be the same as the prior art therapeutic agents in terms of binding specificities and cross reactivities, absent a showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art

and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 18, 19, 23-27, 30, 34-49 and 155 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57, 61-67, 72-80 and 91-117 of copending Application No. 10/029,988. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '988 claims anticipate the instant claims because the antibody multimers of the '988 application bind the same epitopes as the instant antibodies and exhibit the same cross-reactivities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 18-20, 24-30, 32, 34-37, 39, 45, 47, 48, 60, 68-70 and 155 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,132,510 as evidenced by Beer et al (Blood, 1994, Vol. 83, pp. 691-702). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '510 patent anticipate the instant claims. The '510 claims require an Fv molecule which comprises a CDR regions of SEQ ID NO:115 and 114, respectively which is a requirement of the instant claim 25. The '510 claims require that the Fv molecule is able to bind to leukemia cells and cells expressing glycocalicin. Beer et al teach that glycocalicin is the extramembranous portion of GPIbalpha (abstract). Thus the instant claims 30, 32, 34 requiring an antibody which binds to GPIbalpha are satisfied. Claim 9 of the '510 patent requires that the cells expressing the glycocalicin are platelets. the instant claims 68-70 require that the antibody inhibits platelet interactions which would be inherently fulfilled by the antibodies of the '520 patent as evidenced by claim 9 which identifies platelets as cells expressing glycocalicin. Claims 6-8 of the '510 patent require that the Fv antibodies bind to B, T and myeloid lineage leukemias. Instant claim 60 requires that the antibody is capable of increasing the mortality rate of leukemia cells, which would be inherently fulfilled by claims 6-8 of the '510 patent.

Claims 26-30, 32, 34-49, and 155 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-51, and 156, of copending Application No. 10/189,258. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the '258 claims. The instant claims specify "human" antibodies. However the claims in the '258 application are to antibodies from any source which encompass human antibodies. Thus, the instant claims drawn to "human" antibodies can be envisioned from the claims of the '258 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicant's amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
11/27/2006

KAREN A. CANELLA PH.D
PRIMARY EXAMINER